Background Material from Oxitec/Intrexon to Guide USG Only Pre-Meeting

May 11, 2017

Following questions/comments apply to the broader group:

Do USG agencies agree that development of vaccines, diagnostics and vector control technologies should continue to be pursued on an expedited basis to address the threat of Zika?

The purpose of the transfer of OX513A from FDA to EPA is to provide consistent approaches for like products and to expedite the review in the face of the current emergency. The current regulatory path for OX513A anticipates conducting a field trial under FDA permitting authority, initiating a Section 18 emergency use application under EPA authority and then transitioning to EPA jurisdiction prior to the issuance of a Section 18 permit and for a final approval.

FDA Questions

Notwithstanding the contemplated FDA transfer of jurisdiction to EPA, under what circumstances would (or could) OX513A remain under FDA jurisdiction, and if it did, what is the anticipated timeline (based on agency experience) for a field trial, EUA and final approval? How are the agencies ensuring that any transfer to EPA doesn't impede the field trial? (Similar question below as to both EPA and FDA).

What steps is FDA taking to expedite the field trial application of OX513A? Are there any additional steps the agency can take, such as seeking a NEPA waiver from CEQ, to shorten the timeline to ensure the trial begins as early in the summer as possible? Is there any information the company can provide to help FDA reach a decision sooner?

EPA Questions

Assuming jurisdictional transfer to EPA, what is the timeline (based on agency experience) for issuance of an EUP (field trial permit), Section 18 and Section 3 final approval?

The timeline for an EUP appears to be much longer than the field trial path under FDA. **Specifically, what steps is EPA taking to expedite the EUP review? To accelerate product access for state and local governments inquiring about timelines for federal government clearance, can an EUP be issued before protein data is generated?**

EPA officials recently stated that a Scientific Advisory Panel (SAP) may now be under consideration for OX513A, which would add 18-36 months to the review period, delaying final approval for OX513A much longer under EPA than as currently envisaged for an FDA approval. **Given the Zika threat, and the certainty of increasing the number of human victims directly proportional to any delay in suppressing the Zika carrier mosquito, is an SAP required? Who waived the SAP requirement for Wolbachia, and who, if anyone has authority to waive the SAP for the Oxitec alternative, so that this can be added to the state and local arsenals now combatting Zika?**

What steps is EPA currently resolved to take to expedite the Section 18 review of OX513A, and what additional steps could EPA take in this regard? Can a Section 18 be issued prior to the generation of protein data, and whose authority would be needed to accomplish this?

FDA/EPA Questions

If the field trial begins under FDA authority, what steps are the agencies taking to ensure a smooth transition such that the trial is not interrupted by the transfer and the trial does not delay Section 18 approval?

General Question

What can be honestly conveyed to state and local officials responsible for protecting citizens from the Zika virus, as to the Federal government's efforts, and specific timeline, for clearing the Oxitec product for the purpose of suppressing the Aedes Aegypti carrier of this crippling disease?